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Dkt. 67268-A/JPW/AJD/JRM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Norbert Schulke et al.

Serial No. : 10/804,802

Filed : March 19, 2004

For : CD4-IgG2 FORMULATIONS

1185 Avenue of the Americas
New York, New York 10036
December 22, 2005

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (**Exhibit A**), and certain of which are attached hereto as **Exhibits 1-62**, respectively:

1. U.S. Patent No. 5,817,767, issued to Allaway et al. on October 6, 1998;

2. U.S. Patent No. 6,083,478, issued to Allaway et al. on July 4, 2000;

3. U.S. Patent No. 5,116,964, issued to Capon et al. on May 26, 1992;

4. U.S. Patent No. 5,565,335, issued to Capon et al. on October 15, 1996;

5. U.S. Patent No. 6,177,549 B1, issued to Maddon et al. on January 23, 2001;

6. U.S. Patent No. 6,187,748 Bl, issued to Maddon et al. on February 13, 2001;

7. U.S. Patent No. 6,451,313 B1, issued to Maddon et al. on September 17, 2002;

8. U.S. Patent No. 6,034,223, issued to Maddon et al. on March 7, 2000;

9. U.S. Patent No. 6,737,267 B2, issued to Maddon and Allaway on May 18, 2004;

10. U.S. Patent No. 4,664,911, issued to Uhr et al. on May 12, 1987;

11. U.S. Patent No. 5,431,793, issued to Wang et al. on July 11, 1995;

12. PCT International Publication No. WO 88/01304, published February 25, 1988 **(Exhibit 1)**;

13. PCT International Publication No. WO 89/01940, published March 9, 1989 **(Exhibit 2)**;

14. PCT International Publication No. WO 89/02922, published April 6, 1989 **(Exhibit 3)**;

15. PCT International Publication No. WO 89/03222, published April 20, 1989 **(Exhibit 4)**;

16. PCT International Publication No. WO 89/06690, published July 27, 1989 **(Exhibit 5)**;

17. PCT International Publication No. WO 90/01035, published February 8, 1990 **(Exhibit 6)**;

18. PCT International Publication No. WO 91/00360, published January 10, 1991 **(Exhibit 7)**;

19. PCT International Publication No. WO 92/13559, published August 20, 1992 **(Exhibit 8)**;

20. PCT International Publication No. WO 97/04801, published February 13, 1997 (**Exhibit 9**);

21. European Patent Publication No. 0 314 317, published May 3, 1989 **(Exhibit 10)**;

22. European Patent Publication No. 0 394 827, published October 31, 1990 **(Exhibit 11)**;

23. Allaway, G.P., et al. (1995) Expression and characterization of CD4-IgG_2, a novel heterotetramer that neutralizes primary HIV type 1 isolates. AIDS Research and Human Retroviruses 11: 533-539 **(Exhibit 12)**;

24. Allaway, G.P., et al. (1993) Synergistic inhibition of HIV-1 envelope-mediated cell fusion by CD4-based molecules in combination with antibodies to gpl20 or gp41. AIDS Research and Human Retroviruses 9: 581-587 **(Exhibit 13)**;

25. Auffray, C., et al. (1991) CD4-targeted immune intervention: a strategy for the therapy of AIDS and autoimmune disease. Trends Biotech. 9: 124-131 **(Exhibit 14)**;

26. Byrn, R.A., et al. (1990) Biological properties of a CD4 immunoadhesin. Nature 334: 667-670 **(Exhibit 15)**;

27. Capon, D.J., et al. (1989) Designing CD4 immunoadhesins for AIDS therapy. Nature 337: 525-531 **(Exhibit 16)**;

28. Chamow, S.M., et al. (1990) Enzymatic cleavage of a CD4 immunoadhesin generates crystallizable, biologically active Fd-like fragments. Biochemistry 29: 9885-9891 **(Exhibit 17)**;

29. Chowdhury, I.H., et al. (1991) Evaluation of anti-human immunodeficiency virus effect of recombinant CD4-immunoglobulin in vitro: a good candidate for AIDS treatment. Med. Microbiol. Immunol. 180: 183-192 **(Exhibit 18)**;

30. Clark, S.J., et al. (1987) Peptide and nucleotide sequences of rat CD4 (W3/25) antigen: evidence for derivation from a structure with four immunoglobulin-related domains. Proc. Natl. Acad. Sci. USA 84: 1649-1653 **(Exhibit 19)**;

31. Collier, A.C., et al. (1995) Safety, pharmacokinetics, and antiviral response of CD4-immunoglobulin G by intravenous bolus in AIDS and AIDS-related complex. J. Acq. Immune Def. Syn. & Hum. Retrovirol. 10: 150-156

(Exhibit 20);

32. Deen, K.C., et al. (1988) A soluble form of CD4 (T4) protein inhibits AIDS virus infection. Nature 331: 82-4 **(Exhibit 21);**

33. Fahey, J.L., and Schooley, R. (1992) Status of immune-based therapies in HIV infection and AIDS. Clin. Exp. Immunol. 88: 1-5 **(Exhibit 22);**

34. Fisher, R.A., et al. (1988) HIV infection is blocked in vitro by recombinant soluble CD4. Nature 331: 76-8 **(Exhibit 23);**

35. Gauduin, M.C., et al. (1996) Effective ex vivo neutralization of human immunodeficiency virus type 1 in plasma by recombinant immunoglobulin molecules. J. Virol. 70: 2586-92 **(Exhibit 24);**

36. Gilboa, E., and Smith, C. (1994) Gene therapy for infectious diseases; the AIDS model. Trends in Genetics 10: 139-144 **(Exhibit 25);**

37. Goodman, J.W., and Parslow, T.G. (1994) Immunoglobulin proteins. In "Basic & Clinical Immunology", 8th edition (Stites, D.P., et al., Eds.) Appleton & Lange, Norwalk, CT, pp. 66-70 **(Exhibit 26);**

38. Hodges, T.L., et al. (1991) Phase 1 study of recombinant human CD4-immunoglobulin G therapy of patients with AIDS and AIDS-related complex. Antimicrobial Agents and Chemotherapy 35: 2580-2586

(Exhibit 27);

39. Jacobson, J.M., et al. (2000) Single-dose safety, pharmacology, and antiviral activity of the human immunodeficiency virus (HIV) type 1 entry inhibitor PRO 542 in HIV-infected adults. J. Infect. Dis. 182: 326-329 **(Exhibit 28)**;

40. Jacobson, J.M., et al. (2004) Treatment of advanced human immunodeficiency virus type 1 disease with the viral entry inhibitor PRO 542. Antimicrobial Agents and Chemotherapy 48: 423-429 **(Exhibit 29)**;

41. Kahn, J.O., et al. (1990) The safety and pharmacokinetics of recombinant soluble CD4 (rCD4) in subjects with the acquired immunodeficiency syndrome (AIDS) and AIDS-related complex. A phase 1 study. Ann. Intern. Med. 112:254-61 **(Exhibit 30)**;

42. Ketas, T.J., et al. (2003) Human immunodeficiency virus type 1 attachment, coreceptor, and fusion inhibitors are active against both direct and trans infection of primary cells. J. Virol. 77: 2762-2767 **(Exhibit 31)**;

43. Klatzmann, D.R., et al. (1990) The CD4 molecule and HIV infection. Immunodefic. Rev. 2: 43-66 **(Exhibit 32)**;

44. Lasky, L.A., et al. (1987) Delineation of a region of the human immunodeficiency virus type 1 gp120 glycoprotein critical for interaction with the CD4 receptor. Cell 50: 975-985 **(Exhibit 33)**;

45. Litwin, V., et al. (1996) Human immunodeficiency virus type 1 membrane fusion mediated by a laboratory-adapted strain and a primary isolate analyzed by resonance energy transfer. J. Virol. 70: 6437-41 **(Exhibit 34)**;

46. Maddon, P.J., et al. (1985) The isolation and nucleotide sequence of a cDNA encoding the T cell surface protein T4: a new member of the immunoglobulin gene family. Cell 42: 93-104 **(Exhibit 35)**;

47. Moore, J.P., et al. (1990) Dissociation of gpl20 from HIV-1 virions induced by soluble CD4. Science 250: 1139-42 **(Exhibit 36)**;

48. Morrison, S.L., et al. (1984) Chimeric human antibody molecules: mouse antigen-binding domains with human constant region domains. Proc. Nat. Acad. Sci. USA 81: 6851-6855 **(Exhibit 37)**;

49. Murray, J.L., et al. (1985) Radioimaging in malignant melanoma with ^{111}In-labeled monoclonal antibody 96.5. Cancer Research 45: 2376-2381 **(Exhibit 38)**;

50. Nagashima, K., et al. (2001) Human immunodeficiency virus type 1 entry inhibitors PRO 542 and T-20 are potently synergistic in blocking virus-cell and cell-cell fusion. J. Infect. Dis. 183: 1121-1125 **(Exhibit 39)**;

51. Pastan, I., and Fitzgerald, D. (1989) Pseudomonas exotoxin: chimeric toxins. J. Biol. Chem. 264: 15157-

15160 **(Exhibit 40)**;

52. Pastan, I., and Fitzgerald, D. (1991) Recombinant toxins for cancer treatment. Science 254: 1173-1177 **(Exhibit 41)**;

53. Pincus, S.H., et al. (2003) A modified SCID mouse model of HIV infection with utility for testing anti-HIV therapies. Aids Research and Human Retroviruses 19: 901-908 **(Exhibit 42)**;

54. Pincus, S.H., et al. (2003) In vivo efficacy of anti-glycoprotein 41, but not anti-glycoprotein 120, immunotoxins in a mouse model of HIV infection. J. Immunol. 170: 2236-2241 **(Exhibit 43)**;

55. Progenics Pharmaceuticals, Inc. (1999) Progenics identifies novel antibody for inhibiting HIV and presents PRO 542 clinical data. February 3, 1999 Press Release **(Exhibit 44)**;

56. Progenics Pharmaceuticals, Inc. (2000a) PRO 542 reduces HIV viral load in children. February 2, 2000 Press Release **(Exhibit 45)**;

57. Progenics Pharmaceuticals, Inc. (2000b) Progenics reports the structure of HIV entry inhibitor PRO 542. May 15, 2000 Press Release **(Exhibit 46)**;

58. Progenics Pharmaceuticals, Inc. (2000c) Progenics reports PRO 542 and T-20 combination synergistic against HIV. July 12, 2000 Press Release **(Exhibit 47)**;

59. Progenics Pharmaceuticals, Inc. (2000) Progenics starts phase II trial of PRO 542 in HIV infected children. November 28, 2000 Press Release **(Exhibit 48)**;

60. Progenics Pharmaceuticals, Inc. (2001) Progenics enters collaboration with Formatech to develop improved dosing formulations for investigational HIV drug PRO 542. October 26, 2001 Press Release **(Exhibit 49)**;

61. Progenics Pharmaceuticals, Inc. (2002) Progenics' investigational HIV entry inhibitor, PRO 542, reduced viral loads in patients failing conventional therapy. March, 18, 2002 Press Release **(Exhibit 50)**;

62. Progenics Pharmaceuticals, Inc. (2002b) Progenics' HIV entry inhibitor, PRO 542, continues to provide encouraging phase II results. July 8, 2002 Press Release **(Exhibit 51)**;

63. Progenics Pharmaceuticals, Inc. (2002) Progenics reports positive results of completed phase II clinical study of HIV entry inhibitor PRO 542. September 27, 2002 Press Release **(Exhibit 52)**;

64. Progenics Pharmaceuticals, Inc. (2002) Progenics Pharmaceuticals reports third quarter 2002 results. November 4, 2002 Press Release **(Exhibit 53)**;

65. Progenics Pharmaceuticals, Inc. (2003) Progenics presents new findings from a phase-2 clinical trial of PRO 542 HIV entry inhibitor. February 11, 2003 Press Release **(Exhibit 54)**;

66. Ryu, S.E., et al. (1990) Crystal structure of an HIV-binding recombinant fragment of human CD4. Nature 348: 419-426 **(Exhibit 55)**;

67. Schooley, R.T., et al. (1990) Recombinant soluble CD4 therapy in patients with the acquired immunodeficiency syndrome (AIDS) and AIDS-related complex. A phase I-II escalating dosage trial. Ann. Intern. Med. 112: 247-253 (**Exhibit 56**);

68. Shearer, W.T., et al. (2000) Recombinant CD4-IgG2 in human immunodeficiency virus type 1-infected children: Phase 1/2 study. J. Infect. Dis. 182: 1774-1779 **(Exhibit 57)**;

69. Smith, D.H., et al. (1987) Blocking of HIV-1 infectivity by a soluble, secreted form of the CD4 antigen. Science 238: 1704-1707 **(Exhibit 58)**;

70. Till, M.A., et al. (1988) HIV-infected cells are killed by rCD4-ricin A chain. Science 242: 1166-1168 **(Exhibit 59)**;

71. Traunecker, A., et al. (1989) Highly efficient neutralization of HIV with recombinant CD4-immunoglobulin molecules. Nature 339: 68-70 **(Exhibit 60)**;

72. Zettmeissl, G., et al. (1990) Expression and characterization of human CD4: immunoglobulin fusion proteins. DNA and Cell Biology 9: 347-353 **(Exhibit 61)**; and

73. Zhu, P., et al. (2001) Structural flexibility and functional valence of CD4-IgG2 (PRO 542): potential for cross-linking human immunodeficiency virus type 1 envelope spikes. J. Virol. 75: 6682-6686 **(Exhibit 62)**.

The Examiner is respectfully requested to make these references of record in the present application by initialing and returning a copy of the enclosed Form PTO 1449.

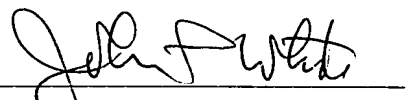
Applicants note that items 1 and 20 were previously cited in an International Search Report issued in connection with foreign counterparts of the subject application. Item 20 is attached hereto as **Exhibit 9**; a copy of the International Search Report is attached hereto as **Exhibit B**.

Copies of items 12-73 listed above are attached hereto as **Exhibits 1-62**, respectively. Copies of items 1-11 listed above, all U.S. Patents or U.S. Patent Application Publications, have not been included as Exhibits in accordance with 37 C.F.R. §1.92a(2)(ii).

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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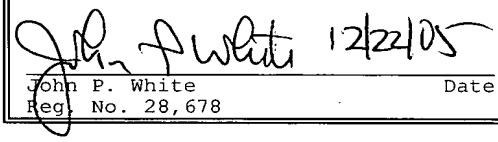

John P. White Date
Reg. No. 28,678

Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Application Number	10/804,802
		Filing Date	March 19, 2004
		First Named Inventor	Norbert Schulke et al.
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Art Unit	
		Examiner Name	
		Attorney Docket No.	67268-A/JPW/ AJD/JRM

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		5,817,767	10/06/1998	Allaway et al.
		6,083,478	07/04/2000	Allaway et al.
		5,116,964	05/26/1992	Capon et al.
		5,565,335	10/15/1996	Capon et al.
		6,177,549 B1	01/23/2001	Maddon et al.
		6,187,748 B1	02/13/2001	Maddon et al.
		6,451,313 B1	09/17/2002	Maddon et al.
		6,034,223	03/07/2000	Maddon et al.
		6,737,267 B2	05/18/2004	Maddon and Allaway
		4,664,911	05/12/1987	Uhr et al.
		5,431,793	07/11/1995	Wang et al.

FOREIGN PATENT DOCUMENTS

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		WO 88/01304	02/25/1988	The Trustees of Columbia University In The City Of New York	
		WO 89/01940	03/09/1989	Biogen, Inc.	
		WO 89/02922	04/06/1989	Genentech, Inc.	
		WO 89/03222	04/20/1989	Dana-Faber Cancer Institute	
		WO 89/06690	07/27/1989	The General Hospital Corporation	
		WO 90/01035	02/08/1990	The United States Of America	
		WO 91/00360	01/10/1991	Medarex, Inc.	
		WO 92/13559	08/20/1992	Progenics Pharmaceuticals, Inc.	
		WO 97/04801	02/13/1997	Genentech, Inc.	
		EPO 0 314 317	05/03/1989	Genentech, Inc.	

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*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds of Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English Language Translation is attached.

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		EPO 0 394 827	10/31/1990	F. Hoffmann-La Roche AG	

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Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		ALLAWAY, G.P., et al. (1995) Expression and characterization of CD4-IgG_2, a novel heterotetramer that neutralizes primary HIV type 1 isolates. AIDS Research and Human Retroviruses 11: 533-539.	
		ALLAWAY, G.P., et al. (1993) Synergistic inhibition of HIV-1 envelope-mediated cell fusion by CD4-based molecules in combination with antibodies to gpl20 or gp41. AIDS Research and Human Retroviruses 9: 581-587.	
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		CHOWDHURY, I.H., et al. (1991) Evaluation of anti-human immunodeficiency virus effect of recombinant CD4-immunoglobulin in vitro: a good candidate for AIDS treatment. Med. Microbiol. Immunol. 180: 183-192.	
		CLARK, S.J., et al. (1987) Peptide and nucleotide sequences of rat CD4 (W3/25) antigen: evidence for derivation from a structure with four immunoglobulin-related domains. Proc. Natl. Acad. Sci. USA 84: 1649-1653.	
		COLLIER, A.C., et al. (1995) Safety, pharmacokinetics, and antiviral response of CD4-immunoglobulin G by intravenous bolus in AIDS and AIDS-related complex. J. Acq. Immune Def. Syn. & Hum. Retrovirol. 10: 150-156.	

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		KETAS, T.J., et al. (2003) Human immunodeficiency virus type 1 attachment, coreceptor, and fusion inhibitors are active against both direct and trans infection of primary cells. J. Virol. 77: 2762-2767.	
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		LASKY, L.A., et al. (1987) Delineation of a region of the human immunodeficiency virus type 1 gpl20 glycoprotein critical for interaction with the CD4 receptor. Cell 50: 975-985.	
		LITWIN, V., et al. (1996) Human immunodeficiency virus type 1 membrane fusion mediated by a laboratory-adapted strain and a primary isolate analyzed by resonance energy transfer. J. Virol. 70: 6437-41.	
		MADDON, P.J., et al. (1985) The isolation and nucleotide sequence of a cDNA encoding the T cell surface protein T4: a new member of the immunoglobulin gene family. Cell 42: 93-104.	
		MOORE, J.P., et al. (1990) Dissociation of gpl20 from HIV-1 virions induced by soluble CD4. Science 250: 1139-42.	
		MORRISON, S.L., et al. (1984) Chimeric human antibody molecules: mouse antigen-binding domains with human constant region domains. Proc. Nat. Acad. Sci. USA 81: 6851-6855.	
		MURRAY, J.L., et al. (1985) Radioimaging in malignant melanoma with ^{111}In-labeled monoclonal antibody 96.5. Cancer Research 45: 2376-2381.	

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Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
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Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Application Number	10/804,802
		Filing Date	March 19, 2004
		First Named Inventor	Norbert Schulke et al.
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Art Unit	
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		PROGENICS PHARMACEUTICALS, INC. (2001) Progenics enters collaboration with Formatech to develop improved dosing formulations for investigational HIV drug PRO 542. October 26, 2001 Press Release.	
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		SMITH, D.H., et al. (1987) Blocking of HIV-1 infectivity by a soluble, secreted form of the CD4 antigen. Science 238: 1704-1707.	
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